Comments Subsequently Received Prior to the January 8th TAC meeting of the PCB Monitoring for Point Source Discharges

Additional Comments:

Bob Steidel, City of Richmond Department of Public Utilities December 18, 2007
Are you aware that DCR is adopting sampling procedures for TMDL in the MS4 regulation? As I read them DCR procedures are counter to your guidance.

Andrea W. Wortzel, Hunton & Williams LLP Received December 20, 2007
Andrea Wortzel called me with questions/concerns about the PCB guidance. She wasn't sure about the process for the regulated community to comment further and our process for wrapping up the document. I wasn't able to help her much there. Anyhow, she did not express any specific concerns but had a general problem from VMA's perspective that there is a lot of background info that they don't typically see in DEQ guidance. She specifically mentioned the "point source" definition. They are concerned that we may have some conflicts with definitions of the similar terms in various regs and questioned whether all the background type info belongs in the guidance memo or a cover memo. With everyone in the manufacturing sector on vacation too, she wasn't sure whether VMA would submit detailed comments but don't be surprised to see the issue mentioned in a broader comment letter. It may do some good to call her after the 1st of the year.

Richard H. Sedgley, AquaLaw PLC received - December 31, 2007
We wanted to note a couple of points concerning the draft Guidance. First, in Guidance Appendix A the statement that "1668A has been proposed for adoption into part 136" is incorrect. It hasn't been. This seems to continue a series of mistaken observations about 1668A.

You may find of interest the presentation attached below, from the November Society for Environmental Toxicology and Chemistry meeting. Although EPA has not published any results from its 2003 interlab study, the authors of the presentation calculate total PCB Quantitation Limits well above those that some labs have claimed, and more consistent with the QLs that the Method itself anticipates. Although the authors are not with EPA, we think it's incumbent on EPA to come forward with any data they have that they believe supports their claimed reporting levels.

As before, we believe the Method, at best, is suitable for qualitative use in the range of the water quality standards.

As to the issue of DEQ letter authority for the generation of new data, the Response to Comments document cites Va Code 62.1-44.19:5.B. That section appears to instruct DEQ as to monitoring, rather than providing extra-permit authority to require it of others.

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July 17, 2007

FILE NO: 54233.000002

BY ELECTRONIC MAIL

Dr. Arthur Butt
Office of Water Quality Programs
Virginia Department of Environmental Quality
629 East Main Street
Richmond, VA 23219

Re: Comments on Draft PCB PS Monitoring Guidance

Dear Dr. Butt:

I am writing to provide comments on the draft PCB Monitoring Guidance ("guidance") currently under review by the technical advisory committee ("TAC"). I have been participating on the TAC as one of the representatives of the Virginia Manufacturers Association ("VMA") and offer these comments on their behalf.

Clarification of Purpose

VMA appreciates the need to gather PCB monitoring data to aid in the development of TMDLs. However, given the ubiquitous nature of PCBs, the developmental nature of Method 1668A (at least for compliance purposes), and the extremely low detection limits associated with that method, VMA echoes the concerns raised by the Virginia Association of Municipal Wastewater Agencies ("VAMWA") about the quality and usage of the data generated using Method 1668A. VMA agrees with DEQ's stated goal of using the data solely for TMDL development purposes, and not for compliance or permitting purposes. For this reason, VMA recommends that item 2 in the introduction of the guidance should be deleted. This provision states that the monitoring data may be used to "strengthen the VPDES permit development process by improving information available to permit writers concerning the toxic discharge for PCBs." In other words, the data generated as part of this monitoring program should be used solely for TMDL development purposes and the reference to permit development should be deleted.

Likewise, the last sentence of the first paragraph on page 2 should be deleted. This sentence reads: "The guidance is needed to promote statewide consistency and efficiencies between the TMDL program and various permitting programs." It is our understanding that there is no current inconsistency between the TMDL and permitting programs with respect to PCBs. This guidance, in effect, creates an inconsistency by recommending the use of a test method not yet approved by EPA for compliance monitoring under the NPDES/VPDES permit program. DEQ should make it very clear that Method 1668A will not be incorporated into permits or used for compliance or enforcement purposes.

Similarly, the last sentence of the first paragraph under section IV should be deleted or modified. The sentence currently reads: "DEQ will determine the reductions needed and consider the following factors: 1) the type of discharges to be monitored; 2) the type of analytical method to be used; and 3) the frequency and duration of monitoring PCBs." This sentence should be conformed with the first sentence in the paragraph, indicating that the monitoring is needed to obtain additional information about PCB sources and to use this information in the development of TMDLs. The sentence could be modified to read: "In order to obtain the necessary information, DEQ will determine appropriate monitoring requirements, taking into consideration the following factors: 1) the type of discharge; 2) the appropriate analytical method; and 3) the necessary frequency and duration of monitoring."

Additionally, the last sentence of the last paragraph of section C should be deleted from the draft guidance. This sentence relates to the development of a pollutant minimization plan as part of the eventual TMDL implementation. Although VMA strongly supports the use of such plans in lieu of numeric effluent limits for pollutants like PCBs and mercury, VMA believes that it is premature to include predictions about how a TMDL will be implemented as part of the monitoring guidance. This guidance should be more narrowly focused on the technical aspects of how and when samples will be collected and analyzed, as well as the types of facilities subject to the monitoring requirement.

Industrial Facilities

The guidance is confusing in its delineation of affected dischargers. VMA believes that the confusion may be caused, in part, by DEQ's attempt to apply one set of monitoring requirements to both industrial and municipal facilities. VMA urges DEQ to distinguish the requirements that apply to these different groups of facilities in sections IV.A and C.

VMA also urges DEQ to clarify which types of industrial facilities will be subject to monitoring requirements. As discussed during the last TAC meeting, certain types of industrial dischargers may be more likely to have PCBs in their effluent discharge than others. DEQ has

indicated that it will specify potential industrial PCB point sources by Standard Industrial Classification ("SIC") Code, and that only "major" industrial facilities within those SIC Codes will be required to monitor. There is also reference to industrial facilities that "comprise a significant volume of flow to the receiving impaired water body." VMA would like to see DEQ more specifically and narrowly define the types of industrial facilities that will be required to monitor for PCBs. For example, New Jersey has defined major industrial facilities for purposes of PCB monitoring requirements, as "any facility which scores 80 or more points on the NPDES permit rating work sheet using the USEPA rating criteria. A facility with less than the required score of 80 may still be classified as a Major facility by the Regional Administrator or the Department. In those situations, the Department shall state the reasons for doing so." N.J.A.C. 7:14A-1.2.

Even with better definition, however, VMA believes that industries should be able to make a written certification that they have no known past or present PCB sources and, through this certification, be exempted from the monitoring requirements. For example, if an industrial facility within a given SIC code can demonstrate that it has no PCBs in its raw materials transformers or other equipment on site (past or present), then that facility should be exempt from the monitoring requirement. An exemption process should be incorporated into the guidance.

Finally, the requirement that each facility subject to the monitoring requirement conduct sampling in both wet and dry conditions does not make sense for many industrial facilities because their discharges are not affected by wet weather conditions. Accordingly, the frequency and number of samples should be determined on a case-by-case basis for industrial facilities.

Credit for Intake Values

Facilities required to conduct PCB monitoring should receive credit for the presence of PCBs in their intake water. Accordingly, it will be important for DEQ to include, in its ambient water sampling, samples near industrial intake pipes. Industrial facilities should not be penalized for the presence of PCBs in their intake water. This concept has been used in the Great Lakes Initiative (40 CFR 132) and by other states, and should be incorporated here.

Flexibility in Sampling Time / Frequency

VMA recognizes that this is guidance, which by definition does not create binding requirements. However, it is important for DEQ to recognize that industrial facilities are extremely diverse in their site conditions and activities (*i.e.*, no one-size fits-all). Accordingly,

it would be worthwhile to include a sentence in the guidance stating that the ultimate requirements (including sampling time and frequency) for PCB monitoring will be determined on a case-by-case basis for industrial facilities, taking into consideration site-specific considerations.

Additionally, the provisions in section C relating to additional samples for verification may be unnecessary in circumstances where, after a review of all of the PCB sampling data collected for a certain water body, the primary source of PCB discharges is determined. For example, if a facility samples and its results are below 500 pg/L, but there are three other facilities that sample and each of their samples indicate the presence of a significant level of PCBs, then there is arguably no need for a verification sample from the first facility.

Standard Operating Procedures for Data Collection and Reporting

It is VMA's understanding that DEQ is in the process of developing standard operating procedures ("SOPs") for sample collection and analysis. These SOPs should be specifically incorporated into the monitoring guidance. It will be very difficult to approve of or apply the monitoring requirements in the guidance without knowing the specific SOPs that will govern such monitoring.

Additionally, there has been much discussion about the use of a J-value for results that are less than the minimum calibration level but greater than the estimated detection limit. It would be helpful if DEQ developed, as part of this guidance, a list of data qualifier flags that will be used in reporting the monitoring results. The Delaware River Basin Commission developed such a list, and that may be a useful starting point for Virginia.

Storm Water Sampling

VMA agrees with many of the comments made at the TAC meeting about the complexity of conducting PCB monitoring at storm water outfalls. VMA is interested to learn more about how such monitoring should be conducted. If, as discussed above, an industrial facility is able to obtain an exemption based on a demonstration that the facility is unlikely to have a PCB source at its site, the exemption should extend to storm water sampling as well.

Additionally, when a facility has more than one storm water outfall, the facility should be able to make a demonstration that the discharge from one of the outfalls is representative of the discharges from the other outfalls based on the industrial activity, significant materials, and management practices and activities within the area drained by the outfalls. Monitoring should not be required at every storm water outfall if this showing can be made. This concept has

been incorporated into Virginia's general permit for industrial storm water discharges (9 VAC 25-151-70), and should be incorporated here.

Due to the ubiquitous nature of PCBs and their longevity in the environment, it is difficult to develop a guidance document outlining when and where monitoring will take place without an opportunity to discuss how the monitoring will be conducted. We hope that as part of the next meeting there will be an opportunity to review DEQ's draft SOPs for sample collection and analysis, as well as data qualifiers, such as the J-value, for analytical results.

Thank you again for the opportunity to provide these comments. If you have any questions about these comments, please feel free to contact me (804-788-8425) or Neil Dalton (540-983-7240).

Sincerely,

Andrea Wortzel

Andrea W. Wortzel

cc: Mr. P. Neil Dalton
Mr. Thomas G. Botkins
Mr. Joseph J. Croce
Mr. Tyrone W. Murray
Mr. Thomas J. Roberts
Mr. Brett A. Vassey

VIRGINIA ASSOCIATION OF MUNICIPAL WASTEWATER AGENCIES, INC.
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July 23, 2007

By Email and U.S. Mail

Mr. Alan E. Pollock
Department of Environmental Quality
Commonwealth of Virginia
P.O. Box 1105
Richmond, Virginia 23218

Arthur J. Butt, PhD
Department of Environmental Quality
Commonwealth of Virginia
P.O. Box 1105
Richmond, Virginia 23218

Re: PCB Monitoring TAC

Dear Alan and Arthur:

On behalf of VAMWA, I ask that you accept for the Department the attached comments on the second TAC meeting and our continuing debate about the usefulness of Method 1668A. I am told that, contrary to the Department's original response to VAMWA's concerns about the Method, it became apparent at the TAC that there has been no interlaboratory validation study. Skipping this important and required step for the expediency of generating TMDL data seems a step backward from the good science that has been the hallmark of the VPDES program.

The current PCB monitoring proposals would shift the burdens of substantial TMDL monitoring from the Department to permittees. This might be acceptable if high quality data were to be generated and then used in a proper manner. However, given the experiences of VAMWA's Northern Virginia members in the Lower Potomac TMDL process, where the Department would ignore its own regulations and attempt to hold permittees responsible for pollutants in intake water, and where the Department appears to agree to an EPA concept of *ad hoc* water quality criteria ("water targets") without the benefit of rulemaking, I do not believe that VAMWA members will be anxious to participate.

As before, VAMWA requests that the Department take a step back in this matter and properly consider the capabilities and limitations of Method 1668A. Any further Department procurement of analyses using Method 1668A, such as for the Roanoke River TMDL, should specifically include a requirement for laboratory submittal of a specific QL demonstration for those analyses.

As always, we appreciate the Department's efforts in support of water quality throughout the Commonwealth.

Sincerely,

Frank W. Harksen Jr./MWA

Frank W. Harksen, Jr.
President

Cc: VAMWA members

VIRGINIA ASSOCIATION OF MUNICIPAL WASTEWATER AGENCIES
COMMENTS ON DEQ'S PCB MONITORING TAC

Second TAC Meeting (June 11, 2007)

July 23, 2007

The following comments address VAMWA's continuing concerns about the use of EPA Method 1668A in concentration ranges for which we believe the Method does not produce quantifiable results.

I. Status of Method 1668A

As VAMWA's earlier comments noted, we are concerned about the use of EPA Method 1668A for PCB congener quantitations in ranges that appear to be well below the accurate range of the Method. We are particularly concerned about the characterization of the Method as producing quantified data of the quality of that produced by Part 136/ 9 VAC 25-31-750 methods, use of the data in a manner otherwise inconsistent with the Department's regulations, and the potential for misuse of the data.

Our April 27 comments focused on the need for a method validation study and use of Method 1668A at a proper Quantitation Level. As you know, use of non-Part 136 methods requires EPA Regional Office approval, and such approval is predicated on documentation of the applicability of the method,[1] done through a validation study. The Department's response was in large part based on the idea that EPA has done a validation study ("EPA has already conducted an interlaboratory method validation study" DEQ Response to Comments Apr. 27, 2007). However, as EPA's representative Ms. Stevie Wilding confirmed on June 11, there has been no validation study. The Department's summary of the June 11 meeting misses the point in merely conceding that "no one present at the meeting had seen the report." There is no such report.

We attach for your reference EPA's Protocol for Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water, which makes it clear that validation is necessary for both methods proposed for Part 136 inclusion and for use of non-Part 136 methods.[2] We also attach a recent EPA memorandum, with which EPA's Water Law Office has agreed, which also states that method validation is required.[3] That simply hasn't occurred with Method 1668A.

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[1] See 40 CFR 136.4 & 136.5.

[2] Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water, EPA 821-B-98-003 (March 1999) (excerpts). Attachment 1.

[3] Memorandum, Regional Approval of Limited Use Methods (EPA Engineering and Analytical Support Branch, June 27, 2007). Attachment 2.

II. The Agencies Appear to be Aggressively Ignoring the Limitations of the Method

As background, we wanted to make sure you are aware that Method 1668A specifies QLs ranging between 50 and 1000 pg/l for the congeners,[4] and generally 500 – 1000 pg/l for the more important higher congeners, not the 8 to 11 pg/l QL that EPA quotes. Although the Method also states that QLs as low as 10 pg/l are possible, that depends on extensive clean methods and a strict Quality Assurance demonstration at that level. It appears to VAMWA that the laboratories are quoting the low QL that they believe EPA wants without a proper QA demonstration. Any future procurement of analyses using Method 1668A, particularly the current program that the Department is pursuing for the Roanoke River TMDL effort, should specifically require a laboratory demonstration of QL for these analyses.

Although the recently reported Method 1668A data generated by the Department and some Virginia permittees reports spike data that are generally within Method parameters, that is not the end of the QA procedures. The determination of a valid QL is a separate QA step from IPR and OPR, blank analyses and any other procedures specified by the Method and standard laboratory practice.[5] In lieu of a QL demonstration, it appears that the analyses are reporting background noise, likely influenced by nonquantifiable concentrations of PCB congeners.

III. VAMWA Does Not View 9 VAC 25-31-190.H as Providing Authority for Requirements for Permittee Generation of New Data

We understand that the Department anticipates permittees voluntarily agreeing to commission and fund Method 1668A analyses, under the specter of a Department demand for data under the Duty to Provide Information section of the VPDES Regulation. VAMWA views this section as authorizing requests for existing information, and not for the generation of new data. We believe data generation requirements are proper pursuant to specific regulations, such as the reapplication data requirements of the VPDES Regulation, and pursuant to specific requirements in individual permits.

IV. The Department's Current Approach Does Not Encourage Permittees to Generate Method 1668A Data

As before, we believe the use of Method 1668A data of the poor quality that has been shown would be a step backwards from good science for both the Department and VAMWA. But, we recognize that the usefulness of PCB

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[4] Method 1668, Revision A (Table 2) (EPA-821-R-00-002, Dec., 1999).

[5] Method 1668A §§ 9 & 13.

TMDLs across the Commonwealth will be limited if there are no data other than those produced by Part 136/9 VAC 25-31-750 methods. We believe there are two options for addressing this.

If EPA wants TMDLs done for PCBs at low levels, it is incumbent on EPA to develop a method that will produce accurate data. Therefore, the first option is to do a proper validation study and establish a valid QL. The second option would be to use the Method while requiring a routine more thorough QA report, recognizing that the results are largely qualitative but usable to establish likely ranges of PCBs in effluents and receiving waters. We believe VAMWA would recommend to its members accepting this approach if the Department agreed to apply its net/gross rule as it is written and to address our other concerns about use of the data that come from our experience with the Lower Potomac TMDL.

Option 1 – Validation Study

We find it disturbing that the agencies appear willing to disregard the mandates of their own regulations because of the expediency of TMDL development. Not unlike this situation, EPA's response to comments critical of Method 1668A in the Delaware River Basin TMDL process was that EPA was doing a validation study. That was in December, 2003,[6] and there is still no validation study and none appears planned.

Option 2 – Qualitative Use of Method 1668A

We believe it would be acceptable to use Method 1668A results, if the laboratory routinely included data on their QA checks at the claimed QLs, if it was acknowledged that the data are of qualitative value and usable to establish ranges in which effluents and surface waters likely include PCBs.

Further, as Department staff comment on June 11 indicated, the Department continues to ignore its own regulation providing for a net/gross analysis where the pollutant is present in intake water. The Department's response to the written comment was that it had never before done a net/gross on sewage effluent. When we pointed out that was exactly what the regulation authorized, there was an equally artificial response.

The simple fact is that all the data in the Lower Potomac example (to the extent that you can conclude anything about PCB concentrations) show that PCBs from the upstream Potomac are present in raw wastewaters, frequently at concentrations similar to or above the reported effluent concentrations. VAMWA's members will be reluctant to accept a procedure that blames those concentrations on their systems.

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[6] Response-to-Comments Document, for the Proposed Total Maximum Daily Loads for PCBs for Zones 2 –5 of the Tidal Delaware River (EPA Regions II & III, Dec. 15, 2003) (excerpts). Attachment 3.

The second point, also from the Lower Potomac experience, is a procedure where EPA and its contractor, with Department agreement, is developing *ad hoc* water quality standards, without the benefit of rulemaking. This procedure appears to effectively hold POTWs responsible for impairments in spite of effluent concentrations below water quality standards. VAMWA's members will not be anxious to generate data that they see as being used in a similar manner.

Accordingly, our second option is to agree on the application of the net/gross regulation and on a more standard water quality approach. Further, to the extent that the Department anticipates looking for PCB "hot spot" sources within POTW collection systems, such hot spots (by definition at much higher concentrations) could be more accurately identified with the approved EPA Method 608 or 625 procedures. The Virginia Manufacturers Association's recommendation concerning a "certification" procedure, where the owner would evaluate its system in light of past uses and surface conditions, should also be incorporated. Under those conditions, we believe that VAMWA would likely recommend to its members a qualified use of Method 1668A.

United States
Environmental Protection
Agency

Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water

March 1999

Attachment 1

U.S. Environmental Protection Agency
Office of Water
Engineering and Analysis Division
1200 Pennsylvania Avenue, NW (4303T)
Washington, DC 20460

EPA 821-B-98-003

March 1999

Foreword

Within the U.S. Environmental Protection Agency (EPA), the Office of Water (OW) publishes test procedures (analytical methods) for analysis of wastewater and drinking water. Listed at parts 136 and 141 of Title 40 of the *Code of Federal Regulations* (CFR), these methods are authorized for use in data gathering and environmental monitoring under the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). These methods have been developed by EPA, by consensus standards organizations, and by others. Many of these methods, especially methods published before 1990, are prescriptive with limited ability to modify procedures or change technologies to accommodate specific situations. There has been a growing awareness within EPA and the analytical community that the requirement to use prescriptive measurement methods and technologies to comply with Agency regulations has unintentionally imposed a significant regulatory burden and created a barrier to the use of innovate environmental monitoring technology.

This document gives specific instructions to external organizations regarding the validation, submission, and EPA approval of applications for the approval of new methods to determine inorganic and organic analytes. EPA anticipates that the standardized procedures described herein should expedite the approval of new methods, encourage the development of innovative technologies, and enhance the overall utility of the EPA-approved methods for compliance monitoring under National Pollution Discharge Elimination System (NPDES) permits and national primary drinking water regulations (NPDWRs).

This document is not a legal instrument and does not establish or affect legal obligations under Federal regulations. EPA reserves the right to change this protocol without prior notice.

All questions regarding the guidelines presented in this document should be directed to:

William Telliard
Analytical Methods Staff
Engineering and Analysis Division (4303-T)
U.S. EPA, Office of Water
1200 Pennsylvania Ave, NW
Washington DC 20460
202-566-1061
202-566-1053 (facsimile)

1.0 INTRODUCTION

1.1 Background and Objectives

1.1.1 Clean Water Act and Safe Drinking Water Act

CWA section 304(h) requires the EPA Administrator to promulgate guidelines establishing test procedures for data gathering and monitoring compliance with published guidelines. EPA's approval of analytical methods is authorized under this section of CWA, as well as the general rulemaking authority in CWA section 501(a). The section 304(h) test procedures (analytical methods) are specified at 40 CFR part 136. They include *Methods for Chemical Analysis of Water and Waste* (MCAWW); the 600- and 1600-series methods; methods published by consensus standards organizations; methods used by the U.S. Geological Survey; methods developed by the environmental community; and other methods referenced in CWA regulations. EPA uses these test procedures to support development of effluent limitations guidelines approved at 40 CFR parts 400 - 499, to establish compliance with (NPDES) permits issued under CWA section 402, for implementation of the pretreatment standards issued under CWA section 307, and for CWA section 401 certifications.

The SDWA requires the EPA Administrator to promulgate National Primary Drinking Water Regulations (NPDWRs) that specify maximum contaminant levels (MCLs) or treatment techniques for listed drinking water contaminants (section 1412). In addition, section 1445(a) of SDWA authorizes the Administrator to establish regulations for monitoring to assist in determining whether persons are acting in compliance with the requirements of SDWA. EPA's approval of analytical test procedures is authorized under these sections of SDWA, as well as the general rulemaking authority in SDWA section 1450(a).

SDWA section 1401(1)(D) specifies that NPDWRs contain criteria and procedures to ensure a supply of drinking water that dependably complies with MCLs, including quality control (QC) and testing procedures to ensure compliance with such levels and to ensure proper operation and maintenance of drinking water supply and distribution systems. These test procedures (analytical methods) are approved at 40 CFR part 141. They include MCAWW methods; the 200-, 300-, and 500- series methods; and other methods referenced in SDWA regulations. EPA uses these test procedures to establish MCLs under SDWA section 1412 and to establish monitoring requirements under SDWA Section 1445(a).

1.1.2 40 CFR 136.4, 136.5 and 141.27

Requirements for approval of alternate analytical techniques (methods) are specified at 40 CFR 136.4 and 136.5 for wastewater methods and at 40 CFR 141.27 for drinking water methods. These requirements are the basis for the Agency's alternate test procedure (ATP) program for water methods. Under the ATP program, an organization may submit an application for approval of a modified version of an approved method or for approval of a new method to be used as an alternate to an approved method. The submitting organization is responsible for validating the new or modified method. The Agency reviews the ATP validation package and, if required, promulgates successful applications in the CFR. Rulemaking is required when a new or revised method is added to the list of approved methods in the CFR. The ATP and rulemaking processes make heavy demands on stakeholder, contractor, EPA, and *Federal Register* resources. These processes can require several months to approve a minor method modification and a year or more to promulgate a major modification or a new technology. Because advances in analytical technology continue to outpace the capacity of OW's method approval program, the program has been

under-utilized and slow to respond to emerging technologies. This protocol is intended to specify a more rapid and less resource intensive process for approval of new technologies.

1.1.3 Description of Document

This protocol details the requirements for approval of new methods to be included at 40 CFR part 136 or 141. A new method is a set of procedures that has been written in the seventeen section standard EPA format as detailed in the *Guidelines and Format for Methods to be Proposed at 40 CFR Part 136 or Part 141*; contains standardized QC elements with associated QC acceptance criteria; employs a determinative technique for an analyte of concern that differs from determinative techniques employed for that analyte in methods previously approved at 40 CFR part 136 or 141 and employs a determinative technique that is as sensitive and/or selective as the determinative techniques in all methods previously approved for the analyte.

The new methods approval program provides chemists with the opportunity to utilize best professional judgement to enhance compliance monitoring. Approval for a new method may be sought when the new method reduces analytical costs, overcomes matrix interferences problems, improves laboratory productivity, or reduces the amount of hazardous materials used and/or produced in the laboratory. The new methods approval program thus can serve as a mechanism for gaining approval of innovative technologies for use in compliance monitoring programs. The protocol described in this document is designed to reduce the barriers to gaining acceptance of new methods, to spur the development and use of new technologies, and to expedite the review and approval process for gaining acceptance of a new method. A method developer may apply to gain approval for the use of a new method for determination of an analyte of interest to the NPDES or NPDWR monitoring programs by developing and validating the new method using either the procedures described in this document or the classical interlaboratory validation procedures provided by organizations such as ASTM[1] and AOAC-International.[2,3] While EPA can be contacted at any point for assistance, EPA's main role will be to review the application for completeness and to determine acceptability. Consequently, EPA will be able to approve new methods for use more quickly and efficiently.

1.2 Tiered System for Validation of New Methods

EPA recognizes that a formal interlaboratory method validation may not be suitable for all situations and may be prohibitively costly to implement, especially for small laboratories and regulated entities. Therefore, EPA has developed a three-tiered, cost-effective approach to method validation that classifies the intended use of a new method and requires a method validation study that reflects the level of use associated with each tier. An applicant would have to determine the most appropriate tier for the new method and develop QC acceptance criteria using the procedures specified in Appendix D of this protocol. The three method validation tiers are listed below.

Tier 1 methods may only be used by a single laboratory (limited-use) for one or more matrix type(s). A matrix type is defined as a sample medium (e.g., air, soil, water, sludge) with common characteristics across a given industrial subcategory. For example, C-stage effluents from chlorine bleach mills, effluent from the continuous casting subcategory of the iron and steel industrial category, POTW sludge, and in-process streams in the Atlantic and Gulf Coast Hand-shucked Oyster Processing subcategory are each a matrix type. Tier 1 validation requires a single laboratory validation study in the matrix type(s) of interest.

Tier 2 methods may be used by all laboratories (nationwide use) for only one matrix type. Validation requires a three-laboratory validation study.

Tier 3 methods may be used by all laboratories (nationwide use) for all matrix types. Validation requires a nine-laboratory validation study.

2.0 APPLICATION REQUIREMENTS

Every new method application shall be made in triplicate and include a completed new method approval application form (provided in Appendix A) with required attachments.

2.1 Submission Addresses

A summary of where to submit new method applications and the approval authorities for each tier level is provided in Table 1.

Table 1: Submission of New Method Applications

TIER	LEVEL OF USE	APPLICANT	SUBMIT APPLICATION TO[1]	APPROVAL AUTHORITY
Tier 1	Limited Use for Wastewater	EPA Regional laboratories	EPA Regional Administrator[2] (Regional ATP coordinator)	EPA Regional Administrator
		States, commercial laboratories, individual dischargers, or permitees in States that do not have authority	EPA Regional Administrator[2] (Regional ATP coordinator)	
		States, commercial laboratories, individual dischargers, or permitees in States that have authority	Director of State Agency issuing the NPDES permit[2]	
Tier 2	Nationwide Use	All applicants	Director, Analytical Methods Staff, EPA Headquarters	EPA Administrator
Tier 3	Nationwide Use	All applicants	Director, Analytical Methods Staff, EPA Headquarters	EPA Administrator

[1] See Appendix B for EPA addresses.

[2] The Regional ATP coordinator may choose to forward Tier 1 (LU) applications to the Director of the Analytical Methods Staff (AMS) for an approval recommendation.

Upon receipt of the application, AMS staff will assign an identification number to the application. The applicant should use the identification number in all future communications concerning the application.

2.2 Application Information

Information required on the new method application form includes: the name and address of the applicant; the date of submission of the application; the method number and title of the proposed new method; the analytes(s) for which the new method is proposed; the type of application (i.e., wastewater, drinking water, or a combined wastewater/drinking water application); the level of use desired (i.e., limited use or nationwide use); the tier level at which the proposed new method will be validated; and, for limited-useapplications, the applicant's NPDES permit number, the issuing agency, the type of permit and the discharge serial number if applicable.

The following items must be submitted with the application: the justification for proposing the new method; the proposed new method prepared in standard EPA format; the method validation study report, including supporting data; and, for nationwide applications that will undergo rulemaking, method development information and documentation that EPA can use in preparing the preamble and docket for the proposed rule.

Before proceeding with the new method validation, the Agency strongly encourages an applicant to submit its validation study plan for EPA review and comment.

The elements required for a complete application at each tier are presented in Table 2. EPA must receive all required application information and attachments before the application is considered complete.

Table 2. Application Requirements

Tier	Level of Use	Application Requirements
Tier 1	Limited Use	• Completed application form • Justification for new method • Method in EPA format • Validation study report
Tier 2	Nationwide Use	• Completed application form • Justification for new method • Method in EPA format • Validation study report • Method development information and documentation
Tier 3		

2.2.1 Justification for New Method

The entity that proposes a new method should provide a brief justification for why the new method is being proposed. Examples include but are not limited to: the new method successfully overcomes some or all of the interferences associated with the approved method; the new method significantly reduces the amount of hazardous wastes generated by the laboratory; or the cost of analyses are significantly reduced when using the new method.

2.2.2 *Standard EPA Method Format*

In accordance with the standard EPA format advocated by EPA's Environmental Monitoring Management Council (EMMC), methods must contain 17 specific topical sections in a designated order. The 17 sections listed in Appendix C to this document are mandatory for all methods. Additional numbered sections, may be inserted after Section 11.0, *Procedure*, as appropriate for a particular method. For more detailed information on the EPA format for proposed methods, see the Guidelines and Format document.[4]

2.2.3 *Validation Study Report*

The applicant must conduct a validation study and provide a comprehensive validation study report with the new method application. The validation study report must include the following elements:

- Background
- Study Design and Objectives
- Study Implementation
- Data Reporting and Validation
- Results
- Development of QC Acceptance Criteria
- Data Analysis/Discussion
- Conclusions
- Appendix A - The Method
- Appendix B - Validation Study Plan (optional)
- Appendix C - Supporting Data (Raw Data and Example Calculations)

These elements are described in Section 3.6.

2.2.4 *Method Information and Documentation to Facilitate EPA Preparation of Preamble and Docket*

For Tier 2 and 3 applications, the new method will be approved by the EPA Administrator through rulemaking. In these cases, the applicant shall provide to EPA information and documentation that will aid EPA in preparing the preamble and docket for the proposed rule that will be published in the *Federal Register*. Information to be provided includes: a detailed background and summary of the method, a discussion of QC acceptance criteria development, and a description and discussion of the interlaboratory method validation study and any other method studies conducted during method development and validation. Specifically, the applicant shall submit information that:

- Defines the purpose and intended use of the method
- States what the method is based upon, noting any relationship of the method to other existing analytical methods and indicates whether the method is associated with a sampling method
- Identifies the matrix(ces) for which the method has been found satisfactory
- Describes method limitations and indicates any means of recognizing cases where the method may not be applicable to the specific matrix types
- Outlines the basic steps involved in performing the test and data analysis
- Describes the QC acceptance criteria development process and gives example calculations

3.0 METHOD VALIDATION

3.1 Introduction

Method validation is the process by which a method developer substantiates the performance of a new method. New methods must be validated to prove that they accurately measure the concentration of an analyte in an environmental sample. If, during a compliance inspection or audit, it is determined that a regulated party is using an unvalidated new method, the data generated by the unvalidated method will be considered unacceptable for compliance monitoring or reporting. The validation requirements listed below were developed to reflect the level of intended use of the method. This is accomplished through a three-tiered approach, as shown in Table 3.

Table 3: Tiered Validation Strategy

Tier Level	Laboratory Use	Applicable to . . .
Tier 1	Single Laboratory (Limited-use or LU)	One or more matrix types from any industry; (Excluding PWSs)
Tier 2	All Laboratories (Nationwide use or NW)	One matrix type within one industrial subcategory; or all PWSs
Tier 3	All Laboratories (Nationwide use or NW)	All matrix types from all industrial subcategories

Under Tier 1, single laboratories will be allowed to validate and use new test methods without the burden of conducting an interlaboratory validation study, whereas new methods intended for multi-laboratory use in a given industrial subcategory (Tier 2) or for multi-laboratory use for all industrial subcategories (Tier 3) require interlaboratory testing.

3.2 Summary of Validation Requirements

EPA has developed a tiered validation approach that coordinates validation requirements with the level of intended use of the new method. Tier 1 (LU) represents validation in a single laboratory, Tier 2 (NW) represents interlaboratory validation in one industrial subcategory, and Tier 3 (NW) represents interlaboratory validation in multiple matrix types. New methods may be used after validation at the appropriate level is performed and formal approval is granted by the appropriate authority. Tier 1 (LU) contains two levels of validation, depending on whether the individual laboratory will be applying the new method to a single matrix type or to multiple matrix types. The Tier 1- Single Matrix Type category allows the laboratory to apply the new method to a single matrix type. The Tier 1- Multiple-Matrix Type category allows a single laboratory to apply the new method to an unlimited number of matrix types after the method has been validated on a minimum of nine matrix types.

Table 4 summarizes the validation requirements for wastewater new methods. Table 5 summarizes the validation requirements for drinking water new methods. Only Tier 2 (NW) validations are applicable

to drinking water because the Office of Ground Water and Drinking Water (OGWDW) no longer approves Tier 1 (LU) new methods and the drinking water program regulates a limited number of matrix types.

Table 4. Summary of Validation Requirements for New Methods for the Analysis of Wastewater [1]

Method Application	Number of		Number of Analyses Required			
	Labs	Matrix types	IPR- reagent water[2]	IPR- sample matrix[3]	MS/MSD	MDL[4]
Tier 1-Single-lab First matrix type	1	1	4	4	0	7
Each additional matrix type (8 max.)	1	1	0[5]	0[5]	2	0[5]
Tier 2-Multi-lab, single matrix type	3	1	12	0	6[6]	21
Tier 3-Multi-lab, multiple matrix types All matrix types	9[7]	9	36	0	18[6]	63

Notes:

(1) Numbers of analyses in this table do not include background analyses or additional QC.tests such as calibration, blanks, etc. Validation requirements are based on the intended application of the method. Nine would be the maximum number of matrix types (or facilities) that would be required to validate a new wastewater method at Tier 1 or 3.

(2) IPR reagent water analyses would be used to validate method performance and to establish QC acceptance criteria for initial precision and recovery (IPR) and ongoing precision and recovery (OPR) for a new method. The required number of IPR analyses, except as noted under footnote 6, would be four times the number of laboratories required to validate a new method because each laboratory would perform a 4-replicate IPR test.

(3) IPR sample matrix analyses would be used to establish QC acceptance criteria for matrix spike/matrix spike duplicate (MS/MSD) recovery and precision for a Tier 1 new method only. IPR sample matrix analyses would not be required for validation of Tier 2 or 3 new methods because this variability data would be obtained from MS/MSD tests.

(4) A method detection limit (MDL) test would be performed in each laboratory using the new method. 40 CFR part 136, Appendix B, requires a minimum of seven analyses per laboratory to determine an MDL. Each lab involved in validation of a new wastewater method would demonstrate that the new method would achieve the detection limits specified in the regulations at 40 CFR parts 136 and/or in another EPA specified documents.

(5) The MDL, reagent water IPR, and sample matrix IPR tests would not have to be repeated after the first matrix type or facility was validated.

(6) The MS/MSD analyses would establish MS/MSD recovery and precision for the new method. The required number of MS/MSD analyses would be two times the number of facilities or matrix types tested.

(7) The number of laboratories and samples would vary if a conventional interlaboratory study is used.

4.0 EPA REVIEW AND APPROVAL

4.1 EPA Review of Applications

All requests for approval of proposed new methods will undergo review by EPA. Limited-use new methods (Tier 1) will be approved through an EPA letter of approval. New methods proposed for nationwide-use (Tiers 2 and 3) will be approved through rulemaking. Proposed test procedures prepared under this protocol should demonstrate an improvement over current EPA- approved methods that offers one or more of the following advantages: better method sensitivity or selectivity, lower analytical costs, fewer matrix interference problems, improvement in laboratory productivity, or reduction in the amount of hazardous materials used and/or produced in the laboratory.

EPA's Analytical Methods Staff (AMS) at EPA Headquarters will review all nationwide-use new methods and will review limited-use applications if requested by the EPA Regional Office or State Agency. AMS may be assisted in its technical review by contractor personnel. When a formal new method application is received, AMS will first check the documentation for completeness. If the documentation is incomplete, AMS will contact the applicant and request missing documentation before proceeding with its review.

At a minimum, an application must include a completed new method application form, the method in EPA standard format (or other standard format - see Section 3.5.1), and a Validation Study Report with supporting data, before AMS will review the package. If these elements are present, AMS will begin an internal review of the new method for scientific merit, consistency, and appropriateness. The internal review at EPA may involve multiple programs and workgroups. Should any problems or questions arise during the review, EPA or its technical support contractor will communicate with the applicant to resolve outstanding issues. Depending on the circumstances, EPA may return the application to the applicant for revision. Internal review of proposed new methods will involve the three steps briefly described below.

The first step of EPA's technical review will evaluate the description of the proposed method and assess the new methods applicability for approval at 40 CFR parts 136 or 141. If the proposed method is not applicable to 40 CFR parts 136 or 141 and/or the method description is not acceptable, EPA will recommend rejection of the application. If this information is acceptable, the evaluation will proceed.

In the second step of EPA's review, the performance of the new method will be evaluated. The performance (sensitivity, precision and recovery) of the method is based on data provided by the applicant and the development of QC acceptance criteria. If method performance is acceptable, the review will continue.

As the third and final step, EPA will perform a detailed audit of the proposed method test data. The evaluation of test data in applications can be accomplished more quickly if machine-readable files of test data (and analysis software where different from EPA software) are provided on floppy disks with the application. Data files should be in IBM-PC compatible format, suitable for input directly into statistical analysis software, such as the Trimmed Spearman-Karber, Probit, Dunnett, and ICP programs.

4.2 Approval Recommendation

EPA will complete its review and notify the applicant of EPA's recommendation. For limited-use applications, the Regional Administrator will issue the formal approval for limited-use of the new method. For all nationwide use applications (Tiers 2 or 3), AMS will notify the applicant of EPA's recommendation, and if the new method is recommended for approval, will initiate the rulemaking process through which the new method is formally approved by the EPA Administrator.

4.3 Rulemaking Process

Using the information provided with the new method application to develop the preamble, EPA will prepare the proposed rule for approval, complete the rule docket, pass the draft rule through internal review at EPA, and submit it to the Office of the Federal Register (OFR) for publication. *Preparation, approval, and publication of a proposed rule generally requires a minimum of four months, and may take longer depending on the nature of the method.* When published, the proposed rule requests public comment and allows a specified comment period, generally 30 to 60 days. At the end of the comment period, EPA will forward any significant comments to the method applicant for technical assistance to EPA in drafting responses to comments. All comments that have scientific or legal merit, or raise substantive issues with the proposed rule, must be answered to complete the rulemaking process.

EPA will review the comment responses provided by the applicant and complete the response-to-comments document for the final rule. EPA will then prepare the final rule, compile the rule docket, and submit the final rule to the OFR for publication. The final rule will state the date that the rule becomes effective, typically 30 days after rule publication. As of this effective date, the method is approved by EPA and will be included in the appropriate table(s) at 40 CFR part 136 and/or 141 in the next CFR update. *It generally requires a minimum of eight months after the proposed rule is published to receive and respond to comments, prepare and process the final rule through internal EPA review, and publish the final rule in the Federal Register.*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 27 2007

MEMORANDUM

OFFICE OF WATER

To: Gerry Sotolongo, Quality Assurance Manager
EPA New England Regional Laboratory

From: Richard Reding, Chief
Engineering and Analytical Support Branch
EAD, OST, Office of Water

Topic: Regional Approval of Limited Use Methods

I am responding to your request for a follow-up to your conference call with our water law attorney, and other Regional Quality Assurance Managers about clarification of the Regional role in the alternate test procedure (ATP) approval process under 40 C.F.R. §136.5. The Water Law Office has reviewed this memorandum and concurs in its legal conclusions. In addition to clarifying Regional roles, I also describe our efforts (and a March 2007 regulation) to streamline approval of modified Clean Water Act (CWA) test procedures (methods.)

As you know, Section 136.5 provides for approval of ATPs in two circumstances. First, the Regional Administrator may approve the request of an individual NPDES discharger for use of test procedures other than those specified in Table I of Section 136.3. Second, an ATP may be approved for nationwide use, if the Administrator proposes to incorporate the new method into Section 136.3 and, after public comment, publishes a final decision to approve the method.

In the first circumstance, applicants may ask a Region to review and approve use of a new method or a modified Part 136 method at their facility. Sometimes we are consulted on these regional reviews and decisions. While we would appreciate being copied on limited use ATPs that the Regions review and approve, we do not need to see the applicant's data.

In the case of methods for which nationwide approval has been requested and Headquarters review has been completed, the regulations would allow limited use before EPA completes the process of national approval via rulemaking. Under EPA's Clean Water ATP program, a developer seeking nationwide approval of an ATP must first complete a multi-laboratory study of the method in representative circumstances that is reviewed by the Office of Water's Office of Science and Technology (OST). If OST determines that the method is both technically acceptable relative to other Part 136 methods, and applicable to CWA programs, the ATP coordinator writes the ATP applicant about this. These letters indicate that EPA should consider rulemaking for nationwide approval and that Regions approve the method under the limited use provisions of 136.5.

For the future, this Office in our ATP letters may indicate when we might conduct a rulemaking. In addition, for the sake of clarity, we also will stress that an ATP method with "interim" approval may be used for compliance monitoring by a facility only after limited use is approved by an EPA Region under Section 136.5, or if EPA has approved it for nationwide use through rulemaking. As you may know, we use the phrase "interim approval" in our ATP letters

Attachment 2

because the regulated community wants to see the word "approved" before considering compliance use of a non-part 136 method.

At the time method developers are notified of favorable action on their methods, we also will notify the Regions and note your authority to issue limited use approvals on a facility by facility basis under 136.5 without further individual review of the discharger's performance data. While Section 136.5 does not specifically provide the basis on which to approve a limited use ATPs -- the "scientific and technical" reasons or basis must be provided for approval or rejection (Section 136.5(b) & (d)) -- the application requirements in Section 136.4 indicate that the applicant must provide "justification" for using test procedures other than Part 136 methods (Section 136.4(c)(3) and explain why the ATP is applicable to the effluents in question (Section 136.4(c)(4)). We see no policy or legal basis for requiring individual applicants to duplicate OST's already thorough review. OST's "interim" determination of the applicability and comparability of the ATP to approved test procedures certainly provides appropriate justification for such approval. In the circumstances, allowing Regional applicants to simplify the approval process by "piggy-backing" on OST's conclusions is legally defensible and, at the least, minimally consistent with reducing unnecessary roadblocks to EPA regulatory action.

We recommend adoption of a simplified approach under Section 136.5 to approving use of ATP methods for individual NDPES dischargers. After the first Regional limited use approval letter, the process for subsequent approval may be much streamlined because the application requirements of Section 136.4(c) (3) and (4) may be met by reference to the Region's earlier approval action. For the reasons explained above, a potential user need not submit lab data to receive a limited use ATP approval letter because a multi-laboratory validation study is a condition precedent to obtaining a favorable ATP letter from OST.

Following Regional approval of its use, an ATP method becomes like any other method used for compliance.[1] Users execute the initial and ongoing demonstration of capability instructions in the method, and document that they routinely run the method correctly. This data is kept on file for inspection at accreditation audits, or submitted if a client requests it. Although Regions or States have authority to request additional data for their limited use determination, such requests generally would not be necessary and are inconsistent with EPA's desire to promote the introduction and use of more effective or accurate methods. We expect that Regions will need to request additional performance data only if there is a significant concern that a specific ATP method would not work for a particular matrix, facility or industry.

I also want to inform you of the new CWA method flexibility amendment (40 CFR Part 136.6) that describes modifications one may make to a Part 136 method without EPA oversight. This amendment was promulgated on March 12, 2007 (72 FR 11200). We believe this action will significantly decrease the number of modifications submitted for ATP review. We recently eliminated about half of our ATP backlog by closing out discrete analyzer modifications that simply automated a manual Part 136 method. When combined with judicious and expedited approval of limited use ATPs, this flexibility should speed the introduction of better technologies. This decrease in the routine ATP burden allows regional and program chemists to focus on new or modified methods that clearly fall outside the scope of 136.6, and therefore justify review under ATP guidelines. Method developers benefit by use of ATP methods without the delay of national rulemaking.

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[1] Should the Regionally-approved method subsequently be proposed for inclusion in 40 CFR Part 136, and receive adverse comment requiring significant revision or withdrawal of the method, Regional approval may need to be reevaluated and possibly withdrawn.

My thanks to you and your Regional colleagues for your cooperation and support as we continue to streamline the methods approval program, and strengthen our partnerships with Regional and State ATP and quality assurance programs.

cc:
Regional Quality Assurance Managers
Mary Smith, Director, EAD
Richard Witt, Water Law Office/OGC
Lemuel Walker, CWA ATP coordinator
Steve Wendelken, SDWA ATP coordinator
Gregory Carroll, OGWDW
Patrick Bradley, OWM
Tom Laverty, OWM

Response-To-Comment Document
for the
Proposed Total Maximum Daily Loads for PCBs
for Zones 2 - 5 of the Tidal Delaware River

U. S. Environmental Protection Agency Regions II and III

with the assistance of
the Delaware River Basin Commission and
the States of Delaware, New Jersey and Pennsylvania

December 15, 2003

Attachment 3

"Response-To-Comment" Document for the Proposed Total Maximum Daily Loads (TMDLs) for PCBs for Zones 2 - 5 of the Tidal Delaware River

1.0 Introduction

U.S. Environmental Protection Agency (EPA) Regions 2 and 3 proposed and opened for comment the four TMDLs for PCBs for Zones 2 - 5 of the Tidal Delaware River on September 2, 2003. EPA acted on behalf of the States of Delaware, New Jersey and Pennsylvania (the "States") and in cooperation with the Delaware River Basin Commission to establish these four PCB TMDLs. Notices also appeared in the three state registers on September 2, 2003. Additional notices were published in regional newspapers. Three informational meetings were held – one in each estuary state – to present the technical basis and overall plan for establishment of these TMDLs and a formal public hearing was convened on October 16, 2003. On October 21, 2003, the public comment period ended. EPA received a total of 289 comments in written form from 30 individuals or entities and orally from 8 individuals at the public hearing. This document presents the detailed responses of the above-mentioned parties to the wealth of public comment on these TMDLs. EPA carefully considered these comments in finalizing the PCB TMDLs.

2.0 Two-Part Presentation of Responses

Five, overarching themes can be identified in the body of public comment. Therefore, EPA, the States and the Delaware River Basin Commission determined that the best approach for responding to the voluminous comments was by preparing a two-part presentation of responses, as follows in this document. In the first part, the five broad themes are identified and responded to with substantive, short-essay responses. In this manner, all of the public's major concerns are addressed. In the second part, every comment received - both in writing and orally – has been enumerated in a table and provided a direct response either by referencing the appropriate "theme response" or by providing additional, targeted information or by both.

3.0 Overarching Themes Found in the Public Comments

The five broad themes uncovered in the public comments and representing major areas of concern are presented on the next pages. Each theme is presented as a paraphrased remark and its respective response follows.

Theme 1

"Are these TMDLs based on a valid tool to describe the relationship between loading and response? Are the allocations correct from the technical, regulatory and legal standpoints?"

Assumptions Used in the Development of the Penta-PCB Model and the TMDLs

Several commenters noted that other source categories (i.e. loads from the open boundaries, gas adsorption, and contaminated sediments) were not included in figures depicting the loading sources of penta-PCBs probably because the model used prescribed boundary and initial conditions to internally compute them. Figures presented in both the model calibration and the TMDL report depict either only the external loads (such as Fig. 2.1, model calibration report) or the loadings minus tributary boundaries and categories such as contaminated sites (Fig. 9, TMDL report). Fluxes and tidal boundary loads have been included in the penta-PCB model and TMDL calculations, and are appropriately computed within the model framework. Where appropriate, and consistent with the context, figures have been modified to include these loadings such as Figures 29 to 32 in the TMDL report.

Inconsistency of Decadal Scale Simulations with Historical Sediment and Fish Data

The expert panel formed by the Commission to guide the development of the penta-PCB model has reviewed the results of the short-term model calibration and the decadal scale consistency check performed by the consultant to the Delaware Estuary TMDL coalition. At a joint meeting of the expert panel and the Commission's Toxic Advisory Committee on November 21, 2003, the panel concluded that based upon the results of the short-term calibration, the model captures the spatial and temporal distributions of the available penta-PCB data, and reflects the current state of the art in applied contaminant modeling. The panel further concluded that additional data and model refinements should be included in the development of the Stage 2 TMDLs. Regarding the purported inconsistencies with the data that were reported when decadal scale model simulations were performed, EPA and the expert panel both concluded that it is not possible to confirm the existence of any trend in the PCB concentrations in surficial sediment due to high data variability, and disagreed with the commenter's interpretation on the performance of the model. Comparison of Figures 5.5 and 5.10 in the model calibration report demonstrate that model output closely mirrors the shape of the hindcast trends selected. The selected hindcast trend may be incorrectly forcing a decreasing trend in simulated sediment and tissue concentrations by forcing a decreasing trend in loads. The expert panel recommended that further analysis of the historical data from surficial sediment and dated cores should be performed in addition to evaluation of the loading trend used for decadal scale model simulations.

As discussed at the joint meeting on November 21, 2003 the expert panel concluded that the present model is acceptable for use in establishing Stage 1 TMDLs. EPA, DRBC and the States agree with this conclusion.

Need for a Food Chain Model to Describe the Relationship Between Water Column PCB Concentrations and Fish Tissue

Several commenters noted that the approach incorporated in the water quality criteria assumed that the fish and water concentrations were at a constant ratio, and that this was not applicable to the present situation in the Delaware Estuary because the recent historical data demonstrated that the ratio of fish tissue PCB concentrations to that of the water column was increasing. A food chain bioaccumulation model was therefore recommended to relate fish tissue PCB concentrations to that in the ambient water column and sediment bed. The U.S. EPA requested that the basis for the Stage 1 TMDLs be the current DRBC human health water quality standards for total PCBs. These standards use a bioconcentration factor (BCF), not a bioaccumulation factor (BAF).

EPA does not agree that the currently available data unequivocally show that the ratio of the fish tissue concentrations of PCBs to the water concentrations of PCBs is changing. Longer term monitoring is needed to ultimately determine whether this ratio is changing or whether perceived changes are normal variability within a currently stable regime. Continued monitoring of fish tissue concentrations in the estuary by the DRBC and the states is planned.

Refinements of the TMDLs in Stage 2 and in future years will likely be based upon different water quality criteria. EPA has issued a new methodology for developing human health water quality standards that recommends the use of BAFs for various trophic levels. DRBC has developed and will be conducting public participation on the revised human health criteria for carcinogens using this new methodology. Wildlife criteria will be developed by the DRBC in the next two years. While the controlling water quality criterion in the future is uncertain, the Stage 2 criterion will most likely be a water-based value. In consideration of these factors, the expert panel recommended at a joint meeting with the Commission's Toxic Advisory Committee on November 21, 2003 a phased approach to the development of a bioaccumulation model. The panel suggested the initial use of either the Thomann or Gobas bioaccumulation models, followed by the development of a bioenergetics model following Stage 2.

Environmentally Wrong to Assign Assimilative Capacity to Sediments

Any process that results in the loss of PCBs from the estuarine ecosystem such as volatilization, burial in sediments, dechlorination and exportation, will provide additional assimilative capacity in the ecosystem. As indicated in the model calibration report, the observed burial rates from dated core samples, sonar scan results, decadal scale consistency check, and professional judgment were used along with observed water column carbon concentrations to check model output. Along with loads and forcing

functions, settling/resuspension rates and decay rates, surface sediment mixed layer depth are determined as part of the model calibration. The approach of considering net burial of carbon (particulate PCBs) as a sink in the determination of the TMDLs is therefore deemed to be appropriate.

Extrapolation of Penta to Total PCBs is an Oversimplification

Since pentachlorobiphenyls (penta-PCBs) were the dominant homolog in fish tissue monitored in the estuary, and since ambient data indicated that throughout the estuary this homolog represents approximately 25 percent of the total PCBs present, the penta-PCBs were selected as a surrogate for total PCBs. Based upon the recommendations of the expert panel formed by the DRBC and a review of the available data, EPA adopted this approach. Further refinement of the total PCB TMDLs using a sum of the ten PCB homologs will occur in Stage 2.

Technical Flaws in Collection of PCB Data

Many commenters have raised issues concerning the analytical methodology required by DRBC and proposed to be utilized in Stage 2 and its applicability to these TMDLs. The DRBC required the utilization of congener-specific analytical methodologies for analysis of various media containing PCBs. This approach is based on the previous monitoring experiences of the DRBC and some of the estuary states for PCBs. Studies from the early 1990's of effluent, ambient water and sediment samples yielded non-detectable results utilizing conventional Aroclor methodology for PCB analysis. However, these results were inconsistent with fish tissue analysis results which indicated elevated levels of PCBs. Further studies were conducted by the DRBC in the mid- and late 1990's utilizing analytical techniques capable of detecting individual congeners which indicated detectable concentrations of PCBs. Analytical methodologies which can detect individual congeners have the following advantages as compared to conventional Aroclor method: lower detection limits, reduced number of false negative results, better characterization of concentrations of individual congeners and estimates of PCB loadings. The finding of this and previous studies support the use of low level congener method, as opposed to Aroclor methods for the identification and characterization of sources of PCBs. Some commenters have argued the applicability of 1668A for these studies, as well as in NPDES permits. We note that the method has undergone a single laboratory validation and is currently undergoing an inter-laboratory study as per EPA protocols. Furthermore, EPA recommended the use of Method 1668A for monitoring for generation of data used to determine TMDLs (EPA letter dated May 31, 2000 from William A. Telliard to Joe Rogan, PECO Energy Company).

Commenters also noted that not enough data was collected from point sources, contaminated sites and non-point sources to support the proposed TMDLs. In all instances, the TMDL is based on the best data available at the time the TMDLs were developed. The data were determined to be sufficient to estimate loads from various source categories, characterize the main stem Delaware concentrations, and develop a linkage between loads and concentrations. Both the hydrodynamic and water quality models were calibrated and the calibration results are provided in supporting documents. Model calibration results were judged scientifically credible and adequate to support development of the Stage

1 PCB TMDL by a panel of independent scientists and modeling practitioners. Refinements to the loading estimation and modeling work will be continued in Stage 2 TMDLs development. In order to quickly initiate the collection of additional data, the DRBC adopted Resolution No. 2003-27 on December 3, 2003. This resolution authorizes and directs the Executive Director to require dischargers and other responsible parties to conduct monitoring and/or other data collection and analyses to further characterize point and non-point loadings of toxic contaminants, including PCBs, to the Delaware Estuary for purposes of developing and implementing TMDLs or actions under the DRBC Water Quality Regulations.

Flaws with Data Interpretation

Commenters have also questioned the use of qualified data and the use of one-half of the detection limit for non-detected congeners in loading calculations. We offer the following rational for the use of qualified data and the use of one-half the detection limit in calculations. Method 1668A defines detected and quantifiable concentrations of each PCB congener by defining Estimated Method Detection Limits (EMDLs) and Estimated Minimum Levels (EMLs). These provide an indication of the concentration of a congener within a sample, and the certainty with which that concentration is known. EMDLs are defined as the lowest concentration at which an analyte can be detected with common laboratory interferences present. EMLs are defined as the lowest concentration at which an analyte can be measured reliably with common laboratory interferences present. Therefore, concentrations greater than the EMDL, although qualified, were used in calculations. Setting non-detect data to ½ the detection limit is a standard and accepted treatment of non-detected data. This treatment is well established in the literature. Since the true concentration of a non-detect sample is somewhere between zero and the detection limit, setting the concentration equal to ½ the detection limit is equally likely to under predict or over predict the true concentration. We offer the following references in support of the use of one-half the detection limit.

1. EPA/540/1-89/002 (RAGS); Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C. 1989.

2. EPA's "Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds; Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. (EPA/600/P-00/001Ag, June 2000, p 57.

3. EPA's Proposal for Control of TEQ in Biosolids - On December 23, 1999 (64 FR 72045), EPA proposed regulations for control of TEQ in biosolids. In the proposal, EPA esta-blished TEQs assuming nondetects of zero, ½ the detection limit, and the detection limit.

Pamela F. Faggert
Vice President and Chief Environmental Officer

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Dominion®

July 20, 2007

JUL 23 2007

Dr. Arthur Butt
Office of Water Quality Programs
Virginia Department of Environmental Quality
629 East Main Street
Richmond, Virginia 23219

Re: PCB Technical Advisory Committee (TAC)
PS Monitoring Guidance Development

Dear Dr. Butt:

Dominion appreciates the opportunity to participate on the above referenced Technical Advisory Committee to assist the Department of Environmental Quality in the development of a guidance document for low level PCB monitoring for point source discharges. This is an important task to help ensure statewide consistency in the PCB TMDL program. While Dominion understands that future sampling using the low level method 1668A will be on a voluntary basis by point source dischargers, we offer the following general comments for consideration to include in the guidance as it is developed over the next few months:

Application

Exemption – With appropriate justification, facilities otherwise required to conduct PCB monitoring should be exempt from sampling if there is sufficient evidence that there are no known past or present PCB sources on site. Accordingly, we support the adoption of an exemption process in the guidance.

Flexibility – Consideration should be given for the allowance of flexibility in sampling times, locations and frequency due to site-specific considerations.

Methodology

J-Value – Consistent with comments raised during the TAC meeting, the assignment of a "J" value for results between detection and calibration levels is appropriate, but a value of 0 should be assigned for those below detection levels.

Standard Operating Procedures – Dominion urges DEQ to consider incorporating sampling protocols that have been developed in other areas, such as the Delaware River or the Potomac River.

Sampling

Intake Values - The guidance should specifically acknowledge that intake sampling may be appropriate to determine ambient levels of PCB. Accordingly, Dominion recommends adding language that credits intake levels of PCBs against sample results for outfalls.

Representative Samples – At most of Dominion's facilities with multiple storm water discharges, representative sampling is allowed for the parameters for which we are required to monitor. Similar allowances should be made in the PCB guidance. Additionally, Dominion has stations with multiple non-contact cooling water discharges that are substantially identical. For these non-contact cooling water discharges we believe that a single outfall should be considered representative of the other outfalls, and a single sample should satisfy the requirements of the guidance.

The Virginia Manufacturers Association has shared their proposed comments with Dominion. We support the comments submitted by VMA, as they are largely inclusive of the issues addressed above.

Thank you for your consideration of these comments. Dominion may provide additional comments as the guidance is developed further. Please contact Scott Reed (804-273-2788, f.scott.reed@dom.com) if you have any questions.

Sincerely,

Pamela F. Faggert

Pamela F. Faggert

Cc: Alan Pollock